OSMONICS
Medical Systems

7848 South 202nd Street
Kent, WA 98032-1345 USA

Phone (253) 395-2200
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JUN 2 6 2003

510(k) SUMMARY

DATE PREPARED: **03 Feb 03**

1. SUBMITTER

Osmonics Medical Systems
7848 S. 202nd Street
Kent, WA 98032-1345

2. CONTACT PERSON

Name: Kristine Kaliszewski
Phone: (253) 395-2200 ext. 4767
Fax: (253) 395-2363
Email: kkaliszewski@osmonics.com

3. DEVICE IDENTIFICATION

Trade Name/Proprietary Name:
Device: Solution Delivery System Local (SDSL), Solution Delivery System Remote (SDSR) and Acid Delivery System (ADS)

Common Name: Mixing and distribution system for bicarbonate and acid concentrates for dialysis

4. CLASSIFICATION NAME AND REFERENCE

Classification Names: Tank, Holding, Dialysis and Accessories

Classification: Class II, 21 CFR 876.5820
Panel: Gastroenterology
Product Code: FIN

5. PREMARKET NOTIFICATION NUMBER: K023011

6. **INDICATION FOR USE:** The Solution Delivery System Local and Solution Delivery System Remote are intended to be used in a hemodialysis facility for mixing and distribution of sodium bicarbonate (bicarb) and the distribution of acid concentrates to remote points of use where they are mixed with purified water to create the dialysate solutions used in hemodialysis. The Acid Delivery System is intended to be used in a hemodialysis facility for the distribution of acid concentrates to remote points of use where they are mixed with bicarb and purified water to create the dialysate solution used in hemodialysis.

7. **DEVICE DESCRIPTION:** The Osmonics Solution Distribution System (SDS) provides semi-automatic mixing of bicarb concentrate and the distribution of bicarb and acid concentrates from storage to hemodialysis patient stations. The mixed bicarb solution is automatically transferred to an elevated reservoir (head tank). The SDS, depending on the model purchased, can transfer up to three different acid concentrates to elevated head tanks from 55-gallon drums or larger bulk acid storage tanks. Bicarb and acid then flow via gravity from the head tanks to the dispensing stations.

8. **STATEMENT OF SUBSTANTIAL EQUIVALENCE:** The Osmonics Solution Distribution System is substantially equivalent in intended use, features, functions, and technological characteristics to the G.E.M. Water Systems International Sodium Bicarbonate Mixers/Delivery Systems (K970674).

9. **PERFORMANCE: SAFETY AND EFFECTIVENESS INFORMATION**
The Solution Delivery Systems have been manufactured and tested to meet the safety requirements of CSA and UL. The SDS systems comply with CAN/CSA C22.2 no. 601-1-M90: Safety of Medical Electrical Equipment, Part I, General Requirements for Safety and UL std No. 2601-1: Safety of Medical Electrical Equipment, Part I: General Requirements for Safety as certified by Canadian Standards Association.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

Ms. Kristine L. Kaliszewski
Regulatory Affairs Manager
Osmonics Medical Systems
7848 S. 202nd Street
KENT WA 98032-1345

Re: K023011
Trade/Device Name: Solution Delivery System Local (SDSL), Solution Delivery System Remote (SDSR), and Acid Delivery System (ADS)
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis systems and accessories
Regulatory Class: II
Product Code: 78 FIN
Dated: May 14, 2003
Received: May 30, 2003

Dear Ms. Kaliszewski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Osmonics Medical Systems
7848 S. 202nd Street
Kent, WA 98032-1345

510(k) Number (if known): K023011

Device Name: Solution Delivery System Local (SDSL), Solution Delivery System Remote (SDSR) and Acid Delivery System (ADS)

Indications for Use Statement

The Solution Delivery System Local and Solution Delivery System Remote are intended to be used in a hemodialysis facility for mixing and distribution of sodium bicarbonate (bicarb) and the distribution of acid concentrates to remote points of use where they are mixed with purified water to create the dialysate solutions used in hemodialysis. The Acid Delivery System is intended to be used in a hemodialysis facility for the distribution of acid concentrates to remote points of use where they are mixed with bicarb and purified water to create the dialysate solution used in hemodialysis.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number: K023011

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023011